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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,840

Applicant(s)

HANDLER, ALFRED M.

Examiner

Gerald G Leffers Jr., PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1636

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 8/16/2004, in which claims 1-19 were cancelled and in which claims 20-24 were added. Claims 20-24 are pending and under consideration in this action.

Response to Amendment

In addition to the amendments to the claims, the response filed on 8/16/2004 comprises a 1.132 Declaration from the inventor stating that he was the sole inventor of the Handler et al reference used in the previous office action to reject claims 1-5, 9-19 as being anticipated under 35 U.S.C. 102(a). This declaration obviates the grounds of rejection recited in the previous action and the rejection is withdrawn. The amendment of the claims to more precisely claim the *D. melanogaster* polyubiquitin promoter has overcome those grounds of rejection made in the previous action over U.S. Patent No. 6,218,185. Any other rejection of record in the previous office action, mailed 5/6/2004, not addressed herein is withdrawn.

This action is FINAL as the new grounds of rejection recited herein were necessitated by applicant's amendment of the claims in the response filed 8/16/2004.

Petition for Color Photographs

Receipt is acknowledged of a petition, filed 5/12/2003, for the acceptance of color drawings in the instant specification. The examiner is still in the process of obtaining the color drawings from the storage facility. A decision on the proposed drawings will be made once the drawings are obtained. If the examiner cannot obtain the color photographs from the storage

Art Unit: 1636

facility, he will call applicant's representative to arrange the delivery of copies to the office.

Receipt is also acknowledged of an amendment to the specification in the response of 8/16/2004 in which the appropriate paragraph was added to the specification concerning the color drawings.

Claim Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 recites, "A vector comprising SEQ ID NO: 6." Claim 23 is directed to the vector of claim 22 wherein the fluorescent protein gene, encoding EGFP, is substituted by another fluorescent protein gene. If the gene encoding EGFP is removed from the vector of claim 22, the vector can no longer comprise SEQ ID NO: 6. Thus, claim 23 is directed to a vector that does not fall within the scope of claim 22.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1636

This is a new rejection necessitated by applicant's amendment of the claims in the response filed 8/16/2004.

Claim 20 is directed to a vector "comprising a nucleotide sequence from a piggyBac transposon and at least one sequence encoding a fluorescent protein wherein said sequence encoding a fluorescent protein is operatively linked to a polyubiquitin promoter obtained from *Drosophila melanogaster*." There is no literal or inherent support for the broad genus of vectors as recited in the rejected claims where the vector comprises "a" nucleotide sequence from a piggyBac transposon. As written, the claim reads on a vector comprising literally any dinucleotide sequence found in a piggyBac transposon sequence so long as it also comprises a sequence encoding a fluorescent protein operatively linked to the polyubiquitin promoter. This results in the claim reading on an enormous genus of vectors for which there is no literal support in the instant specification. For example, original claim 1 at least recites that the sequence encoding the fluorescent protein is inserted into the piggyBac sequence. Therefore, claims 20-21 are rejected for comprising impermissible NEW MATTER.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicant's amendment of the claims in the response filed 8/16/2004.**

Art Unit: 1636

The specification teaches that SEQ ID NO: 6 describes the plasmid pB[PUB-nls-EGFP]#257. There appears to be no literal or inherent support in the originally filed claims or specification for a vector "comprising" SEQ ID NO: 6 or pB[PUB-nls-EGFP]#257. For this reason, claim 22 is rejected as comprising impermissible NEW MATTER.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/101,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. **This is a new rejection necessitated by applicant's amendment of the claims in the response filed 8/16/2004.**

The claim of the '840 application is directed to:

A transformation system comprising a vector having SEQ ID NO 6 wherein said vector contains a piggyBac transposon digested with BglII, a promoter region of a polyubiquitin gene, and a nuclear localizing sequence of an SV40 virus.

Art Unit: 1636

The specification of the '840 application discloses that SEQ ID NO: 6 describes plasmid pB[PUB-nls-EGFP]#257 (e.g. Figures 5-6 and SEQ ID NO: 6 in the sequence listing). The NLS described as part of the pB[PUB-nls-EGFP]#257 vector is an SV40 NLS (e.g. see page 20 of the '840 specification).

The claims of the instant application are directed to a vector comprising "a" nucleotide sequence from a piggyBac transposon and at least one sequence encoding a fluorescent protein wherein the sequence encoding the fluorescent protein is operatively linked to a polyubiquitin promoter obtained from *Drosophila melanogaster*. The piggyBac transposon can be modified by the deletion of about 748 bp by BglII-HpaI digestion. Claim 24 is directed to a composition for transformation that comprises a first DNA comprising a non-transposon DNA sequence inserted between a pair of inverted repeats of a piggyBac transposon wherein the piggyBac transposon is modified by deletion of about 748 bp by BglII-HpaI digestion, and at least one sequence encoding a fluorescent protein under control of a polyubiquitin promoter obtained from *D. melanogaster*. The composition further comprises a second DNA encoding a piggyBac transposase under control of a heat-shock inducible promoter.

The instant specification also teaches pB[PUB-nls-EGFP]#257 (e.g. Figures 5-6 and SEQ ID NO: 6 in the sequence listing). As such, the remaining claim of the '840 application necessarily anticipates claims 20-22. Further, in order to understand the metes and bounds of what is encompassed by SEQ ID NO: 6, the skilled artisan would necessarily have to look to the specification of the '840 application in order to determine those examples that provide support for the claimed vector (e.g. how to make and use the claimed sequence). One would have necessarily recognized that the plasmid vector recited in claim 1 of the '840 application is

Art Unit: 1636

intended for use with a helper vector encoding a piggyBac transposase under control of an inducible promoter (e.g. a heat-shock inducible promoter). In addition, the skilled artisan would necessarily recognize that any fluorescent protein known in the art could be substituted for the EGFP protein encoded by the pB[PUB-nls-EGFP]#257 vector. Therefore, the claim of the '840 application either anticipates or otherwise makes obvious each of the pending claims. Further, if a patent were to issue on the instant claims and the rights thereto assigned to a different entity from that holding the rights to the claim of the '840 application, the opportunity for harassment by multiple assignees would improperly arise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed in the response of 8/16/2004 to a similar grounds of rejection over the claims of the '840 application have been fully considered but they are not persuasive. The response requests that the rejection be held in abeyance until such time as allowable subject matter is indicated in the instant application. The response further indicates a terminal disclaimer will then be filed in a timely fashion. Until such time as a terminal disclaimer is filed, or until the claims of the '840 application no longer anticipate or make obvious the instant claims, the rejection stands.

Claims 20-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,773,914 B1 (published 8/10/2004 and having the same inventive entity as the instant application). Although the

Art Unit: 1636

conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. **This is a new rejection that is necessitated by applicant's amendment of the claims in the response filed 8/16/2004.**

Claim 1 of the '914 patent is directed to a vector having the nucleotide sequence of SEQ ID NO: 6. The phrase "having the nucleotide sequence of SEQ ID NO: 6" is interpreted as being closed language equivalent to "consisting of". The specification of the '914 patent discloses that SEQ ID NO: 6 describes plasmid pB[Pub-nls-EGFP]#257 (e.g. Figures 5-6 and SEQ ID NO: 6 in the sequence listing).

The claims of the instant application are directed to a vector comprising "a" nucleotide sequence from a piggyBac transposon and at least one sequence encoding a fluorescent protein wherein the sequence encoding the fluorescent protein is operatively linked to a polyubiquitin promoter obtained from *Drosophila melanogaster*. The piggyBac transposon can be modified by the deletion of about 748 bp by BglII-HpaI digestion. Claim 24 is directed to a composition for transformation that comprises a first DNA comprising a non-transposon DNA sequence inserted between a pair of inverted repeats of a piggyBac transposon wherein the piggyBac transposon is modified by deletion of about 748 bp by BglII-HpaI digestion, and at least one sequence encoding a fluorescent protein under control of a polyubiquitin promoter obtained from *D. melanogaster*. The composition further comprises a second DNA encoding a piggyBac transposase under control of a heat-shock inducible promoter.

The instant specification also teaches pB[Pub-nls-EGFP]#257 (e.g. Figures 5-6 and SEQ ID NO: 6 in the sequence listing). As such, the issued claim of the '914 patent necessarily anticipates claims 20-22. Further, in order to understand the metes and bounds of what is

Art Unit: 1636

encompassed by SEQ ID NO: 6, the skilled artisan would necessarily have to look to the specification of the '914 patent in order to determine those examples that provide support for the claimed vector (e.g. how to make and use the claimed sequence). One would have necessarily recognized that the plasmid vector recited in claim 1 of the '914 patent is intended for use with a helper vector encoding a piggyBac transposase under control of an inducible promoter (e.g. a heat-shock inducible promoter). In addition, the skilled artisan would necessarily recognize that any fluorescent protein known in the art could be substituted for the EGFP protein encoded by the pB[PUb-nls-EGFP]#257 vector. Therefore, the claim of the '914 patent either anticipates or otherwise makes obvious each of the pending claims. Further, if a patent were to issue on the instant claims and the rights thereto assigned to a different entity from that holding the rights to the '914 patent, the opportunity for harassment by multiple assignees would improperly arise.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1636

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636


GERRY LEFFERS
PRIMARY EXAMINER

ggl